



**BILLING CODE: 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[60Day-16-16CO]**

**[Docket No. CDC-2015-0099]**

**Proposed Data Collection Submitted for Public Comment and  
Recommendations**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Notice with comment period.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment for Developing a Self-Management Tool for Individuals with Systemic Lupus Erythematosus (SLE), to assess the value of a tool aimed to enhance

the ability of persons with SLE to effectively manage their condition.

DATES: Written comments must be received on or before [**INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER**].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0099 by any of the following methods:

Federal eRulemaking Portal: [Regulation.gov](http://www.Regulation.gov). Follow the instructions for submitting comments.

Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

*Instructions:* All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to [Regulations.gov](http://www.Regulations.gov), including any personal information provided. For access to the docket to read background documents or comments received, go to [Regulations.gov](http://www.Regulations.gov).

Please note: All public comment should be submitted through the Federal eRulemaking portal ([Regulations.gov](http://www.Regulations.gov)) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection

plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: [omb@cdc.gov](mailto:omb@cdc.gov).

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

### **Proposed Project**

Developing a Self-Management Tool for Individuals with Systemic Lupus Erythematosus (SLE) - New - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

Systemic Lupus Erythematosus (SLE) is an autoimmune disease in which the immune system produces antibodies to cells within the body

leading to widespread inflammation and tissue damage. SLE has a variety of clinical manifestations and can affect joints, skin, the brain, lungs, kidneys, and blood vessels. Effective SLE management depends not only upon clinical interventions, but also on self-management—those things done on a day-to-day basis to manage SLE. SLE self-management requires gaining essential knowledge, skills, and confidence to manage the condition.

CDC previously launched a two-year project called *"Filling a Gap: Creating Educational Program, Tools, or Materials to Enhance Self-Management in Systemic Lupus Erythematosus"* to identify and address the needs of lupus patients in practicing effective self-management. The purpose of this project is to develop a SLE self-management tool to improve the ability of people living with lupus to manage their condition.

The proposed information collection will assess a SLE self-management tool that is in development to ensure that the tool is usable and useful to members of the target audience. The tool is expected to be comprised of multiple SLE self-management resources that may include, but are not limited to: education resources about fatigue management, pain management, healthy diet, and exercise; symptom trackers; medication trackers; appointment calendars; resources about communication with family, friends, and co-workers

about SLE; and strategies for coping with depression and anxiety. CDC plans to make the tool available in an electronic format (web-based or a native mobile application) and will consider making it available as a printed resource, depending on the feedback obtained during the testing process.

The information collection will also gauge the needs of the target audience(s), tool format and delivery method(s), and the tool's clarity, relevance, salience and appeal. A series of focus groups with women with a diagnosis of SLE, and one-on-one telephone interviews with men with a diagnosis of SLE will be conducted to assess the tool. The same discussion guide will be used for all information collection. The estimated burden per response for participating in a focus group discussion is 2 hours. The estimated burden per response for a discussion conducted via telephone interview is 45 minutes. Respondent burden also includes 2 hours for reviewing the draft SLE self-management tool in advance of the focus group meeting or telephone interview.

OMB approval is requested for one year. Participation is voluntary and there are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Women with SLE diagnosis	Screeners	192	1	10/60	32
	Review of the CDC SLE Self-Management Tool	128	1	2	256
	Discussion Guide	128	1	2	256
Men with SLE diagnosis	Screeners	40	1	10/60	7
	Review of the CDC SLE Self-Management Tool	20	2	2	40
	Discussion Guide	20	1	45/60	15
	Total				606

Leroy A. Richardson  
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Office of Scientific Integrity  
Office of the Associate Director for Science  
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